DIAGNOSTIC KIT FOR DETERMINATION OF IGA CONCENTRATION

OS – IgA

INTRODUCTION

Immunoglobulins (Igs) are the instrumental proteins of immunity. Immunity is a property of the lymphoid system which is made of organs (spleen, thymus, bone marrow) and of cells (lymphocytes). Circulating immunoglobulins are secreted in the blood by B lymphocytes and they thereby export far-away the specific biological functions of humoral immunity. Immunoglobulin A (IgA) is the major Ig found in secretions, playing a major role in the protection of the respiratory, genitourinary, and gastrointestinal tracts against infection.

METHOD PRINCIPLE

The IgA present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum is proportional to IgA concentration in the sample.

REAGENTS

Package

1-Reagent 1 x 44.5 ml 2-Reagent 1 x 10.5 ml

Buffer (1-Reagent) stored at 2-25°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Protect from light and avoid contamination!

Concentrations in the test

Tricine buffer (pH 8.0); PEG; sodium chloride; anti human IgA antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for the HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative.
 Avoid contact with skin and mucous membranes.

SPECIMEN

Serum.

Specimen without lipemia or hemolysis is recommended.

Specimen can be stored up to 3 days at 2-8°C or up to 6 months at -20°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

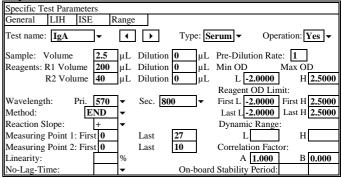
1-Reagent and 2-Reagent are ready to use.

For reagent blank 0.9% NaCl is recommended.

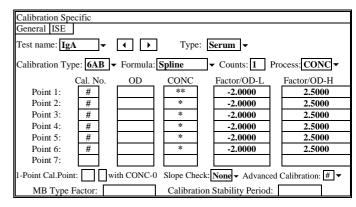
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APPLICATION

Reagent ID: 044



Specific Test Parameters									
General LIH ISE Range									
Test name: IgA ▼									
Value/Flag: # ▼ Level L: # Level H: #									
Normal Ranges:									
	Age L	Age F	I						
Sex	Year Mont	h Year	Month	L	H				
1. # ▼	# #	#	#	#	#				
2. # ▼	# #	#	#	#	#				
3. # ▼	# #	#	#	#	#				
4. # ▼	# #	#	#	#	#				
5. # ▼	# #	#	#	#	#				
6. # ▼	# #	#	#	#	#				
7. None Selected # #									
8 Out of Range # #									
L H									
Panic Value:	#		#	Unit: g/l I	Decimal Places: 2				



- # User defined
- * Calibrator value
- ** Saline should be used as calibrator 1

REFERENCE VALUES 4

REI EREI (CE (IIECES				
adults	0.40 - 3.50 g/l			
children (1 year – 12 years)	0.15 – 2.50 g/l			
children (1 month – 12 months)	0.20 - 0.90 g/l			

It is recommended for each laboratory to establish its own reference ranges for local population.

OUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended.

The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Olympus AU400, Cobas Mira and Hitachi 911. Results may vary if a different instrument is used.

■ **Measurement range:** 0.02 g/l to 8 g/l.

Specificity / Interferences

Haemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

Precision

Repeatability (run to run)	Mean	SD	CV
n = 10	[mg/dl]	[mg/dl]	[%]
level 1	123.1	1.6	1.3
level 2	214.8	2.2	1.0
level 3	297.2	3.2	1.1

Reproducibility (day to day)	Mean	SD	CV
n = 10	[mg/dl]	[mg/dl]	[%]
level 1	117.2	4.1	3.5
level 2	220.8	5.7	2.6
level 3	300.8	8.5	2.8

Method comparison

A comparison between IgA values determined at Olympus AU400 (y) and at ADVIA 1650 using 24 samples gave following results: y = 0.8251 x + 0.0717 g/l;

R = 0.9902 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- Bergstrom, K. & Lefvert, A.K. Scand.J.clin.Lab.Invest. 40 (1980) 637
- Norberd W. Tietz, ed.: Tietz Clinical Guide to Laboratory Tests, sd. ed. W.B. Saunders Company., (1990).
- 3. Burtis C.A., Ashwood E.R., Bruns D.E., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders., (2006).
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Date of issue: 08. 2013.

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